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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/880,199	06/13/2001	Cornelis Theodorus Verrips	F7544(V)	6098

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UNILEVER INTELLECTUAL PROPERTY GROUP
700 SYLVAN AVENUE,
BLDG C2 SOUTH
ENGLEWOOD CLIFFS, NJ 07632-3100

EXAMINER

HENDRICKS, KEITH D

ART UNIT	PAPER NUMBER
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1761

DATE MAILED: 02/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/880,199

Applicant(s)

VERRIPS, CORNELIS
THEODORUS

Examiner

Keith Hendricks

Art Unit

1761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6,12-14,19, 21-25 and 27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 12-14,19 and 22 is/are allowed.
- 6) ☒ Claim(s) 6,21,23-25 and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(i) Claims 6, 24-25 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Meister et al. (US PAT 6,010,725). Meister et al. is herein incorporated as cited at page 6 of the February 25, 2004 Office action.

Applicant's arguments filed November 23, 2005 have been fully considered but they are not persuasive. At pages 6-7 of the response, applicant states that "The Office points to no teaching in Meister et al concerning subjecting either the sprayed dried bacteria or the food product containing the bacteria to any treatment that specifically renders the *Lactobacillus* bacteria non-viable and incapable of inducing substantial fermentation let alone the step of pasteurization."

This is not deemed persuasive for the reasons of record. Reference is made to page 5 of the instant specification, which defines the term "non-viable *Lactobacillus* bacteria" as those "of which substantially all or all bacteria are incapable of growing under the appropriate growing conditions of said *Lactobacillus* strain." The Meister et al. reference, again, discloses a process and resulting food product which yields "at least 1% survival of the microorganisms" after drying. See col. 5, lines 55-61, where the initial composition contains more than 10^8 cfu/g (10^{10} cfu/ 100g), and after drying (i.e. pasteurization or heat treatment) "more than 10^6 cfu/g [10^8 cfu/ 100g] are still active and alive." This amounts to a mere 1% of viable bacteria present in the composition, which also means that 99% are non-viable. This reads upon the specification-defined term of "non-viable *Lactobacillus* bacteria" where "substantially all or all bacteria are incapable of growing under the appropriate growing conditions of said *Lactobacillus* strain" (emphasis added). Note that the recitation of the bacterial property in claim 25, actually amounts to a "product by process", within the process claim 24. Such a recitation of the method of making the product utilized within the process claim (claim 24), must result in a structural difference between the claimed invention starting product and the prior art starting product in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the claimed process and would reasonably meet the claimed property limitations, which it does, then the claim is anticipated as

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stated. In other words, a bacteria pasteurized in line for 30 seconds at 72°C would not appear to patentably differ from those disclosed in the reference.

(ii) The previous rejection under this statute to Lee et al. (US PAT 3,794,739) is withdrawn. Although the bacteria are stated to be rendered non-viable within the reference, (acidic) fermentation may still occur when certain conditions of temperature and pH are met. In support, (a) applicant's specification at page 5, lines 14-24 defines "appropriate growing conditions", (b) the claims state that no substantial fermentation will occur, and (c) page 6 of the specification defines "no substantial fermentation" as a drop in pH of 0.1 units or more, such as by post-acidification. This is what occurs in the Lee et al. reference when the product is introduced to an environment which falls into "appropriate growing conditions", and thus the rejection is withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6 and 21, 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Froseth et al. (US PAT 6,592,915), in view of Meister et al. (US PAT 6,010,725).

Applicant's arguments filed November 23, 2005 have been fully considered but they are not persuasive. At pages 7-8 of the response, applicant states that "this combination of references would not have led to applicant's claimed invention." Applicant also argues the points previously addressed with regard to the Meister et al. reference. Further, "applicants submit that the combination of Froseth et al and Meister et al does not support a prima-facie case of obviousness because this combination would not have contained all of the elements present in applicant's claimed invention."

This is not deemed persuasive for the reasons of record. As previously stated on the record, Meister et al. discloses that a culture of microorganisms is mixed with a liquid preparation of a food

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composition, such as milk, or one from meat, fruits or vegetables (col. 4), which is subsequently spray-dried to form a dried food composition containing amounts of both viable and non-viable bacteria.

Froseth et al. disclose the production of layered cereal bars containing ready-to-eat (RTE) cereal, wherein “the basic physical composition of the cereal bar is that of a ‘sandwich’ composed of two cereal layers with a visible center or middle layer, e.g., a creamy milk-filling layer.” The bar may contain various components and additives, where it is stated that “additives further include nutrient and health additives such as vitamins, minerals, encapsulated biologically active components, nutraceuticals..., probiotic bacteria sprinkles (e.g., lactobacillus or acidophilus)... protein powders, powdered milk fractions, protein or satiety additives...and other similar health-enhancing additives”[underlining added]. The use of milk powder in the cereal bar is mentioned throughout Froseth et al.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In response to applicant's argument, it is noted that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

In response to applicant's statement that “this combination of references would not have led to applicant's claimed invention,” it is maintained that it would have been obvious for one of ordinary skill in the art to have utilized the known probiotic bacteria (*Lactobacillus*)-containing powdered milk preparation of Meister et al. within the layered cereal bar of Froseth et al., which contained a “milk-filling layer”, and which specifically suggested the use of “probiotic bacteria sprinkles (e.g., lactobacillus or acidophilus)”, “powdered milk fractions,” “and other similar health-enhancing additives.” It would not have involved an inventive step for one skilled in the art to have utilized this known preparation. Further, both compositions provide their stated and known contributions, and thus the combination of references reads upon the instantly-claimed invention.

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Allowable Subject Matter

Independent claim 14, and those dependent therefrom, claims 12-13, 19 and 22 are allowed, as previously indicated on the Notice of Allowance dated September 13, 2004.

Examiner's Note: Regarding the journal article to Ouwehand et al. ("The Health Effects of Cultured Milk Products...", of record), it is noted that the reference discloses fermented yoghurts containing either viable, or non-viable *Lactobacillus* bacteria. However, those yoghurts containing the non-viable bacteria were first fermented by the bacteria, and then rendered non-viable, thus not meeting the instant claim limitations. See pg. 755, col. 2, where it refers to "both fermented products and fermented-then-pasteurised products."

Conclusion


Applicant's amendment (of claims 12-13 and 21) necessitated the new ground(s) of rejection presented in this Office action, i.e. that of including claims 12-13 and 21 within the appropriate rejections. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith Hendricks whose telephone number is (571) 272-1401. The examiner can normally be reached on M-F (8:30am-6pm); First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on (571) 272-1398. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


KEITH HENDRICKS
PRIMARY EXAMINER